Andrew Technologies, LLC
Herbert Crane
Vice President RA & Qa
3 Haddon Avenue
Haddonfield, New Jersey 08033

June 9, 2021

Re: K121218
Trade/Device Name: Hydrasolve Console Sterile Treatment Kit Reusable Cannula, 4mm Dia, 26 Cm Length, 3 Aperture Reusable Cannula, 4mm Dia,
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Herbert Crane:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 13, 2012. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter dated: December 13, 2012

Andrew Technologies, LLC
% Mr. Herbert Crane
Vice President, Regulatory Affairs and Quality Assurance
3 Haddon Avenue
Haddonfield, New Jersey 08033

Re: K121218
Trade/Device Name: Hydrasolve Console Sterile Treatment Kit Reusable Cannula
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU
Dated: November 12, 2012
Received: November 13, 2012

Dear Mr. Crane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use

510(k) Number (if known): K121218

Device Name: **HydraSolve™ Lipoplasty System**

Indications For Use:

The HydraSolve™ Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring. The HydraSolve™ Lipoplasty System is indicated for use in aesthetic body contouring.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121218

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1.4 510(k) Summary of Safety and Effectiveness

DEC 1 3 2012

Submitted by:	Herbert Crane Vice President Regulatory Affairs and Quality Assurance
Address:	Andrew Technologies 3 Haddon Avenue Haddonfield, NJ 08033
Telephone:	(959) 502-1907
Facsimile:	(856) 433-8092
Date of Submission:	1 April 2012
Classification Name:	Suction Lipoplasty System (21 CFR 878.5040)
Trade or Proprietary or Model Name:	HydraSolve™ Lipoplasty System
Legally Marketed Devices:	Phaser Lipoplasty System (K092066)

Device Description:
The Andrew Technologies HydraSolve™ Lipoplasty System is a liposuction system used to perform body contouring. It is designed to perform selective tissue extraction through a cannula that utilizes pressurized, heated, and pulsed saline solution in addition to suction.

The device includes the HydraSolve™ Console which contains within its durable case: a user interface, controller, power supply, and Phaser™ energy transfer systems (both heat and pressure). The system also includes a tumescent infusion component which is compatible with commercial off-the-shelf (COTS) tumescent cannulae and tubing. The device also includes the Sterile Treatment Kit consisting of a pumping mechanism, heat exchanger and tubing and a reusable limited-use handpiece with integral cannula. The device interfaces with COTS waste canisters and suction tubing.

Indications for Use:
The HydraSolve™ Lipoplasty System is intended to be used for liquefaction and aspiration of localized subcutaneous fatty deposits for the purpose of aesthetic body contouring.

The HydraSolve™ Lipoplasty System is indicated for use in aesthetic body contouring.

Summary of testing to demonstrate safety and effectiveness
Non-clinical test data was used to support the decision of safety and effectiveness. Clinical testing was not necessary. Non-clinical testing consisted of performance testing of the new cannulae design.

Conclusion
The information provided in this submission demonstrates that the device is substantially equivalent to the predicate devices.